

### **REMARKS**

Applicants have reviewed and considered the Office Action mailed on September 12, 2003, and the references cited therewith.

Claim 1 is amended. Claims 1-3, 14, 15, 19, 28 – 31 are now pending in this application.

#### **Subject Matter of Amendment**

The subject matter of the amendment of claim 1 is supported by the disclosure on page 3, line 14-16 and page 15 of the specification.

#### **Information Disclosure Statement**

Applicants repeat their request regarding the Information Disclosure Statement and corresponding 1449 Form they submitted on August 5, 1998. Applicants respectfully request that initialed copies of the 1449 Forms be returned to Applicants' Representatives to indicate that the cited references have been considered by the Examiner.

#### **§102 Rejection of the Claims**

The Examiner has rejected claims 1-3, 14, 15, 19 and 28-31 under 35 USC § 102(b) as being anticipated by Okada et al. The Examiner asserts that the intermediate emulsion used by Okada to make microcapsules anticipates the subject matter of Applicants' pending claims.

Applicants respectfully submit that their claims, as amended, overcome this rejection.

Applicants have amended their claims to indicate that the emulsion they claim is a low viscosity emulsion. According to Applicants' description at page 3, a low viscosity emulsion is one having a water-like consistency.

The Examiner points to Okada's abstract for a disclosure of Okada's intermediate emulsion. According to this abstract, Okada's emulsion includes an inner aqueous layer of a water soluble drug and a drug retaining substance. His oil layer contains a polymer. Thus, Okada's water layer includes at least three components: water, a water soluble drug and a drug

retaining substance. Okada does not explain in his abstract the nature or function of his drug retaining substance, but he does so at col. 4. Okada states that the drug retaining substance causes the water layer to assume a viscous, semi-solid consistency or is one that provides such a consistency when under the influence of external factors. In other words, Okada's aqueous layer is highly viscous.

Applicants' claims now contrast with this Okada requirement of high viscosity. Applicants emulsion is of a low viscosity. For this reason, Applicants' biologically active mixture of drug and aqueous medium does not contain any material that would render it viscous as Okada's drug retaining substance does for his aqueous layer.

For this reason, Applicants submit that their amended claims are not anticipated by Okada. Okada requires the presence of a component, the drug retaining substance, that is excluded from Applicants' claims by reason of Applicants' amendment.

For this reason, Applicants submit that their claims, as amended, are patentable over Okada.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney ((612) 373-6939) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743

Respectfully submitted,

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By his Representatives,

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Date

Nov 12, 2003

By

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12<sup>th</sup> day of November, 2003.

Dawn M. Poole

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Signature